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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,798	03/06/2002	Amanda S. Schilling	83202	6616

7590

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EXAMINER
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SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/090,798

**Applicant(s)**

SCHILLING ET AL.

**Examiner**

Dr. Kailash C. Srivastava

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,7,10-16 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7,10-16 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

1. Request for continued examination (i.e., RCE) under 37 CFR §1.114, including the fee set forth in 37 CFR §1.17(e), was filed in this application on 17 December 2004 after a Final action mailed 17 August 2004. Since this application is eligible for continued examination under 37 CFR §1.114, and the fee set forth in 37 CFR §1.17(e) has been timely paid, the finality of the previous Office action mailed 17 August 2004 has been withdrawn pursuant to 37 CFR §1.114. Applicants' submissions filed on 17 November and 17 December 2004 has been entered. Accordingly, an RCE has been established and the action on RCE follows.
2. Applicants' responsive Amendment "D" filed 17 November 2004 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

## **CLAIMS STATUS**

3. Claims 2-3, 6, 8-9 and 17-22 have been cancelled.
4. Claims 1 and 4-5 have been added.
5. Claims 1, 4-5, 7, 10-16 and 23 are pending and are examined on Merits.

## ***Claim Rejections Under 35 U.S.C. § 112***

6. Claims 1, 4-5, 7, 10-16 and 23 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicants regard as the invention for the reasons of record at page 2, item 8 in Office Action mailed 17 August 2004.

In response to the rejection to Claims 1, 4-5, 7, 10-16 and 22-23 under 35 U.S.C. § 112, second paragraph in the Office Action mailed 17 August 2004, applicants argue that applicants' have consistently asserted, as originally filed, as well as in various places in the specification that applicants claims are directed to "rapid decontamination of a contaminated area particularly for applications to military operations and the like" and "rapid decontamination depends on the criteria set for "functional cleanup of a contaminated area"". Applicants further argue that in numerous cited examples, applicants have shown that rapid decontamination may vary from less than fifteen minutes to within 24 hours, or "other time periods that promote usefulness of areas or articles for their intended purpose" and since amended Claim 1 encompasses specific ranges for dipicolinic acid, the term, "rapid" is further defined.

Applicant s' arguments filed 17 November 2004 in regard to rejections made in the Office Action mailed 17 August 2004 have been fully and carefully considered, but they are not persuasive for the reasons of record and the additional reasons discussed *infra*.

Recitations, "rapid" and "rapidly" are indefinite as presented, because those recitations describe/represent an event taking place at a time earlier than an event of equal effect and magnitude. Therefore, the criterion for evaluating the rapidness of that event is not merely a function of the strength of the solution (i.e., dipicolinic acid, in the instant case) being applied to observe the effect, even though a certain concentration of dipicolinic acid might contribute to that attribute. The measure of rapidity or rapidness is the time taken for that concentration of that given solution/treatment to produce the manifested effect (i.e., germination or decontamination) that is observed. Thus, the units to establish the rapidity or rapidness of a treatment in contrast to another treatment is time taken for the "test" treatment to manifest the effect being observed. Applicants to note that in the rejection cited *supra*, Examiner has clearly stated how the recitations, "rapid" and "rapidly" should be defined, i.e., "in appropriate scientific units and definitions" (See, Office Action mailed 17 August 2004, Page 2, item 8, Lines 8-9). In applicants' arguments cited above, applicants have recited the metes and bound for the recitations "rapid" and "rapidly" in specification in the terms that the Examiner has just discussed, however, those metes and bounds have not been claimed. Although claims are read in the light of specification, the specification language can't be brought in to the claim unless those limitations or definitions are clearly stated within the claim language.

7. In view of applicants' amendment filed 17 November 2004, following are new rejections to Claims 1, 4-5, 7, 10-16 and 23 under 35 U.S.C. §112, second paragraph.

8. Claims 1, 4-5, 7, 10-16 and newly presented Claims 22-23 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

- Recitations, "rapidly" and "rapid" render Claim 1 vague and unclear because these recitations, in and of itself, do not adequately delineate their metes and bounds. Recitations "rapidly" and "rapid" are relative terms and are subjective and therefore, do not establish any metes and bounds to distinguish those terms from another term. Applicants should clearly define metes and bounds for the terms "rapidly" and "rapid" in appropriate scientific units and definitions. Applicants might find the discussion presented at item 7 *supra* useful to establish the metes and bounds for the recitations "rapidly" and "rapid".

- Phrase, "50% w/w to about 90%w/w water" at Claim 10, Line 2, renders that Claim vague, and therefore indefinite, because it is unclear as to what is the reference for that percentage? Whether that percentage is with respect to the weight of the entire composition comprising dipicolinic acid and calcium chloride, or in relation to a particular component (e.g., dipicolinic acid or calcium chloride) of the composition, or what? Appropriate correction/definition is required. Applicant may consider as guidance the language from Claim 14 to establish that relationship.

All other claims depend directly or indirectly from the rejected claims (e.g., Claim 1) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

### ***Claim Rejections – 35 U.S.C. § 102***

9. Claims 1, 4-5, 7, 10-13, 16 and 23 stand rejected under 35 U.S.C. §102(e) as anticipated by Baugh et al. (U.S. Patent 6,656,919) for the reasons of record in the Office Actions mailed 05 March and 17 August 2004.

In response to art rejections under 35 U.S.C. §102(e) cited *supra* in the above-cited Office Actions (i.e., mailed on 05 March and 17 August 2004), applicants argue that Baugh et al's anticipatory reference is obviated over amended Claim 1, because amended Claim 1 recites the limitation of concentration of dipicolinic acid in range of "about 10 mM to about 150 mM".

Applicant's arguments filed 17 November 2004 in regard to rejections made in the Office Action mailed 17 August 2004 have been fully and carefully considered, but are not persuasive for the reasons of record cited *supra* and the additional reasons discussed *infra*.

Baugh et al. clearly and distinctly teach the instantly claimed concept of concurrently or sequentially treating the bacterial endospores with a germinating and a germicidal solution (Column 5, Lines 14-24) to sterilize a surface or render said surface free of biologically alive/ viable bacterial endospores. Additionally, Baugh et al. teach a germinant solution comprised of adenine, L-alanine, calcium, dipicolinate, glucose and various organic or inorganic anions, and cations in distilled water. Baugh et al. further teach that upon contact with a germinant that does not initially contain dipicolinic acid, with induction of germination, dipicolinic acid is released from the spores into the germinant solution and acts as a germinant for remaining un-germinated spores (Column 7, Lines 30-33). The concentrations of dipicolinic acid, calcium chloride and water in Baugh et al's germinating solution would inherently be within the instantly claimed range, because Baugh et al's method employs the same steps and same ingredients as instantly claimed. Furthermore, instantly recited amended claim 1 is analogous to Baugh et al's teachings, because said Claim 1 does not recite a single dipicolinic acid concentration

(e.g., 60 mM or 0.6 mM), and therefore renders the possibility to choose or pick from the ingredients and concentrations thereof. Baugh et al's germicidal solution, additionally, comprises same ingredients as claimed instantly and those ingredients are art-known bactericidal compound(s) or mixtures of such compounds with surfactants and peroxide compounds (e.g., benzoyl and hydrogen peroxides, see Baugh et al., Column 8, Line 26 to Column 12, Line 55). Thus, Baugh et al. explicitly and inherently teach a method to sterilize materials or surfaces contaminated with biological spores comprising same steps and components as are recited in the instantly claimed invention. Therefore, the recited Claims are deemed anticipated by Baugh et al.

### ***Claim Rejections - 35 U.S.C. § 103***

10. Claims 1, 4-5, 7, 10-16 and 23 remain rejected under 35 U.S.C. § 103 (a) as obvious over Baugh et al. (U.S. Patent 6,656,919) in view of Paidhungat et al. (Journal of Bacteriology, 2000, Volume 182, Pages 2513-2519), Baker et al (U. S. Patent 6,506, 803) and are further obvious over Clouston (U.S. Patent 3,617,178) in view of Paidhungat et al. (Journal of Bacteriology.2000, Volume 182, Pages 2513-2519) and Baker et al (U. S. Patent 6,506, 803) for the reasons of record in the Office Actions mailed 05 March and 17 August 2004.

In response to the art rejections in Office Actions cited *supra*, applicants argue that the claimed invention is unobvious over the cited references, because the cited references do not disclose or suggest, or provide motivation to arrive at the presently claimed invention. Citing several examples from the specification of instant application, applicants further argue that Baugh et al. reference does not particularly point out a given combination of a germinant and Examiner cited secondary references do not remedy that deficiency because those references do not address applicants' claimed invention as amended, because applicants' amended claims are directed to "rapid decontamination of a contaminated surface" resulting from spore germination within a limited amount of time (i.e., 15 minutes) when the contaminant is treated with a particular germinant comprised of a certain composition in a certain concentration (i.e., DPA-Ca (0.6 mM giving 67.17% spore germination). Applicants further argue that combined teachings from examiner-cited prior art references does not "provide a basis to select dipicolinic acid and calcium ions over other germinants"

Applicants' arguments regarding rejections to Claims 1, 4-5, 7, 10-16 and 23 **under** 35 U.S.C. §103(a) in Office Actions mailed 05 March and 17 August 2004 have been fully and carefully considered but are not deemed to be persuasive because of the above cited discussion under items 7 and 10 of present Office Action, for the reasons of record at pages 3-7, item 9 of the Office Action mailed 05 March 2004 and at pages 3-4, items 9-10 of the Office Action mailed 17 August 2004 and further in view of

Figure 4 at Page 2517 of Paidhungat et al. which clearly teaches that a combination of 60 mM each of dipicolinic acid and  $\text{Ca}^{+2}$  gives maximum spore germination which would be the motivation for an artisan of ordinary skill to select a mixture of dipicolinic acid and calcium ions at a concentration of 60 mM for each ingredient from Baugh et al's teachings.

In response to applicants' arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, those reasons have been discussed above and also cited pages 3-7, item 9 of the Office Action mailed 05 March 2004 and at pages 3-4, items 9-10 of the Office Action mailed 17 August 2004. Furthermore, a rejection under 35 U.S.C. § 103 (a) based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention (*Ex parte Raychem Corp*, 17 U.S.P.Q. 2d 1417).


## CONCLUSION


11. For reasons abovementioned, no Claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 8:15 A.M. to 6:45 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (571) 272-0926 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1651  
(571) 272-0923  
February 28, 2005

  
RALPH GIVENS  
PATENT EXAMINER  
6-28-05